K123937

MAY 2 3 2013

510(k) Summary

23-May-13

Atom Medical Corporation
3-18-15, Hongo, Bunkyo-ku
Tokyo, Japan 113-0033

Tel – 011-81-3-3815-3632
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Official Contact: Tsuyoshi Sugino – Regulatory Affairs Manager

Proprietary or Trade Name: Atom Transcapsule V-707

Common/Usual Name: Neonatal Transport Incubator

Classification Name/Code: FPL – neonatal transport incubator
CFR 880.5410

Device: Atom Transcapsule V-707

Predicate Devices: Air-Shields (Draeger) TI500 Isolette – K941106

Device Description:
The Atom Transcapsule V-707 is a closed-type transport incubator for neonatal and premature infants intended to transport low birth weight infants and neonates. It is intended to be used in hospitals, delivery suites, NICU, and transport.

The Transcapsule V-707 controls temperature based on air temperature within the incubator. The front panel shows set temperature and the actual temperature. The heat source is electrically powered and can be set between 23.0 to 38.0°C in 0.1°C increments. The measured temperature within the incubator has a range of 20.0-42.0°C in 0.1°C increments with an accuracy of +/- 1.0°C. It can also show skin temperature of the infant between 30.0 and 42.0°C in 0.1°C increments with an accuracy of +/-0.3°C.

The Transcapsule V-707 can be mounted in a variety of mechanical configurations, the HL Stand for transport and Cabinet Stand for internal hospital use are typical examples, see Section 11 for further details. The HL Stand for transport and the Cabinet Stand for internal hospital use (and oxygen gas cylinder) are not included in this submission.

The Transcapsule V-707 consists of a hood, a main body, a control panel and an external power pack which provides DC power to the incubator. The external power pack also contains batteries to allow for operation when external power is lost. The battery is automatically kept charged when there is an external source of power provided to the device. Battery status (charging and capacity) is indicated on the power pack.

The device provides audible and visual alarms for: High temperature, set point, power failure, fan, system failure, silence, skin temperature probe, low voltage (when the voltage from the battery or the external DC power source falls to approx.10.5V).

The device complies with IEC 60601-1, IEC 60601-1-2 and IEC 60601-2-20.

Indications for Use:
The Atom Transcapsule V-707 is a closed-type transport incubator for neonatal and premature infants intended to transport low birth weight infants and neonates.

Environment of Use: Hospitals, delivery suites, NICU, and transport

Comparison to Predicate

	Proposed Transcapsule V-707	**Predicate K941106 Air-Shields (Draeger) TI500 Isolette Infant Incubator**
Indications for Use	The Atom Transcapsule V-707 is a closed-type transport incubator for neonatal and premature infants intended to transport low birth weight infants and neonates.	Specific indications as submitted to the FDA are unknown. Intended use is equivalent.
Environment of use	Hospitals, delivery suites, NICU, and transport	Hospital, NICU
Patient Population	Infant and neonates	Premature infants
Technology	Electrically heated and controlled on air temperature	Electrically heated and controlled on air temperature
Features and Performance Characteristics		
Overall dimensions	Main Body: 95(W) X 44(D) X 42(H) cm Power Pack: 29(W) X 17.5(D) X 25(H) cm Alternate Power Pack: 35(W) X 20(D) X 33(H) cm Mattress – 55(W) x 28(D) x 2.5(H) cm	52.7(W) X 95.9(L) X 50.8(H) Mattress – 74(W) x 36(D) x 2(T) cm
Weight	Main Body and Power Pack approximately 32kg	49kg
Major components	Hood Main body Power Pack	Hood Main body
Power	100-240 VAC 47-63 Hz or 47-440Hz 220 or 280VA max 11.0- 14V DC 10A	110/120 V, 50/60/400 Hz - 220/240 V, 50/60/400 Hz 11-13/26-30 VDC 200W
Operating conditions	Temperature: 10-30 °C RH - 30-75%	Temperature: Not specified RH - 0-95%

	Proposed Transcapsule V-707	**Predicate K941106 Air-Shields (Draeger) TI500 Isolette Infant Incubator**
Maximum load capacity	IV Pole ~ 3 kg	Not specified
Features and Performance Characteristics (continued)		
Accessories / optional components	Skin Temperature Probe Access port covers Infant Fixing Band IV Pole	Skin Temperature Probe Accessory Shelf IV Pole Infant restraint straps High Hood, Pressure Regulator and flowmeter Humidity Pad
Control modes	Automatic based on incubator air temperature	Automatic based on incubator air temperature
Skin Temperature Measurement Range	30.0 and 42.0°C in 0.1°C increments with an accuracy of +/-0.3°C	Not specified
Incubator air temperature setting range	23.0 to 38.0°C in 0.1°C increments	22 - 38°C
Display range	Skin - 30.0 - 42 °C in 0.1°C increments, Accuracy - $\pm$ 0.3 °C Air - 20.0 – 42.0 °C Accuracy - $\pm$ 1.0 °C	Skin – Not specified Air – Not specified
Heater output	0 – 100% in 10 increments	Not specified
Warm-up time	Approximately 40 min @ 25°C	$\leq$ 60 min @ 25°C
Alarms	High temperature Set point Skin Temperature Probe Fault	High temperature Heater temperature Skin temperature probe fault
Humidity	N/A	Passive
Oxygen supply	$\geq$ 60% @ 10 Lpm	21% to 58% minimum
Environment CO_2 concentration in the hood	< 0.5% 10cm above center of mattress at 750 ml/min	Not specified
Other alarms	Fan System failure Power failure Low voltage	Fan System failure Power failure

	Proposed **Transcapsule V-707**	**Predicate** **K941106** **Air-Shields (Draeger) TI500 Isolette Infant Incubator**
Safety and Performance testing		
Performance testing has been performed per the following standards	IEC 60601-1 (1988) – Medical Electrical Equipment - Part 1: General Requirements for Safety+A1 +A2Amendment 2 IEC 60601-1-2 : 2007– Medical Electrical Equipment - Part 1-2: General requirements for Safety- Collateral standard: Electromagnetic compatibility Requirements and tests (Edition 3) IEC 60061-2-20 (1996) – Amendment 1 - Medical Electrical Equipment - Part 2: Particular Requirements for the Basic Safety and Essential Performance of Infant Transport Incubators	Not specified

Substantial Equivalence Rationale
The Atom Transcapsule V-707 is viewed as substantially equivalent to the predicate device because:

Indications –
- Based on marketing literature equivalent

Technology –
- Identical technology and design

Materials –
- The materials in patient contact are identical to previously cleared Atom Medical Devices

Environment of Use –
- Similar to predicate – Air-Shields (Draeger) TI500 Isolette – K941106

Nonclinical Performance Testing –
Performance testing has been performed to verify requirements have been met and in accordance with FDA recognized standards. The proposed device met and passed all testing criteria.

Substantial Equivalence Conclusion -
The sponsor has demonstrated through performance testing, design and features, and non-clinical testing that the proposed device and predicate have been found to substantially equivalent.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

May 23, 2013

Atom Medical Corporation
C/O Mr. Paul E. Dryden
President
ProMedic, Incorporated
24301 Woodsage Drive
BONITA SPRINGS, FL 34134

Re: K123937
Trade/Device Name: Atom Medical Transcapsule V-707
Regulation Number: 21 CFR 880.5410
Regulation Name: Neonatal Transport Incubator
Regulatory Class: II
Product Code: FPL
Dated: April 15, 2013
Received: April 16, 2013

Dear Mr. Dryden:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

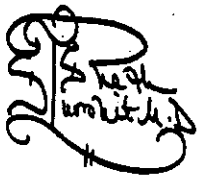
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



Tejashri Purohit-Sheth, M.D.
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FOR

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Division of Anesthesiology, General Hospital,
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Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number: K123937

Device Name: Atom Medical Transcapsule V-707

Indications for Use:

The Atom Transcapsule V-707 is a closed-type transport incubator for neonatal and premature infants intended to transport low birth weight infants and neonates.

Environment of use – Hospitals, delivery suites, NICU, and transport

Prescription Use XX (Part 21 CFR 801 Subpart D) **or** **Over-the-counter use __** (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Sajjad H. Syed

Digitally signed by Sajjad H. Syed
DN: c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People, cn=Sajjad H. Syed, 0.9.2342.19200300.100.1.1=2000601742
Date: 2013.05.23 09:32:23 -04'00'

(Division Sign-Off)
Division of Anesthesiology, General Hospital Infection Control, Dental Devices

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